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### An unrecognised and growing worldwide problem in healthcare

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# OVERDIAGNOSIS: AN UNRECOGNISED AND GROWING WORLDWIDE PROBLEM IN HEALTHCARE

## PREDIAGNOSTICIRANJE: NEPREPOZNANA IN RAZŠIRJENA SVETOVNA TEŽAVA V ZDRAVSTVU

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Editorial

### ABSTRACT

**Keywords:**  
overdiagnosis,  
overdetection,  
disease mongering

Overdiagnosis is the diagnosis of deviations, abnormalities, risk factors, and pathologies that in themselves would never cause symptoms (this applies only to risk factors and pathology), would never lead to morbidity, and would never be the cause of death. Therefore, treating an overdiagnosed condition (deviation, abnormality, risk factor, pathology) cannot, by definition, improve the patient's prognosis, and can therefore only be harmful.

Overdiagnosis is an extremely harmful and big problem all over the world, and the problem is increasing. This is especially the case in high-income countries, where more sensitive tests, more testing, more screening and earlier diagnosis is in focus, and more of the same will be implemented in the future. Moreover, disease definitions have been and are still being widened, plus thresholds for treating, e.g. risk factors, have been and are still being lowered. Finally, disease mongering is growing, because it is cheaper and faster to invent new "diseases" than new pharmaceutical drugs.

From the definition of overdiagnosis it can be reasoned that a patient who has been correctly diagnosed and a person who has been overdiagnosed can have the same kind of pathologies. Therefore, at the level of the individual person or patient it can never be verified whether he or she has in fact been correctly diagnosed or overdiagnosed. Therefore, the complexity, dilemmas and pitfalls in understanding what overdiagnosis really is so succinctly captured by this quote from the Danish philosopher Søren Kirkegaard (1813-55): 'Life can only be understood backwards; but it must be lived forwards'.

### IZVLEČEK

**Ključne besede:**  
prediagnosticiranje,  
pretirano odkrivanje,  
napihovanje bolezni

Postavljanje nepotrebne diagnoze je diagnosticiranje odstopanj, nepravilnosti, dejavnikov tveganja in patologij, ki same po sebi nikoli ne povzročajo simptomov (to se nanaša le na dejavnike tveganja in patologije), nikoli ne prehajajo v bolezen ter niso nikoli vzrok za smrt osebe. S tega vidika zdravljenje zmotno prepoznane stanja (odstopanje, nepravilnost, dejavnik tveganja, patologija) po sami definiciji ne more izboljšati napovedi pacientovega zdravja ter mu lahko le škoduje.

Prediagnosticiranje je izjemno škodljiva in razširjena težava v svetu, sam pojav pa se hitro širi. Predvsem je prisotno v državah z visokimi prihodki, kjer izvajajo presejalne programe, več vrst testiranj in imajo občutljivejše teste, v ospredju pa je predvsem zgodnje odkrivanje bolezni in postavljanje diagnoze. V prihodnosti bo tega vse več. Definicije bolezni se vse bolj razširjajo, meje začetka zdravljenja, na primer dejavnikov tveganja, se pa še vedno nižajo. Napihovanje bolezni je vse pogostejše, saj je ceneje in hitreje ustvariti nove »bolezni« kot izdelati nova farmacevtska zdravila.

Iz same definicije je prediagnosticiranje lahko upravičeno le tako, da imata pacient s pravilno diagnozo in oseba, ki so ji postavili napačno diagnozo, enako vrsto patologij. Tako lahko na stopnji posameznih pacientov ugotovimo in preverimo, če so prejeli pravilno ali pretirano diagnozo. Zapletene dileme in pasti pri razumevanju postavljanja zmotne diagnoze je zelo jedrnatopovzeto v citatu danskega filozofa Sørna Kirkegaarda (1813-1855): »Življenje lahko razumemo samo za nazaj, živeti pa ga je treba naprej«.

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Overdiagnosis is the diagnosis of deviations, abnormalities, risk factors, and pathologies that in themselves would never cause symptoms (this applies only to risk factors and pathology), would never lead to morbidity, and would never be the cause of death (1). Therefore, treating an overdiagnosed condition (deviation, abnormality, risk factor, pathology) cannot, by definition, improve the patient's prognosis, and can therefore only be harmful (2). Overdiagnosis is often mistaken from overtreatment and overuse; however, these are three separate concepts with some overlap: Treatment of overdiagnosed conditions is one category of overtreatment. Another type of overtreatment is when the best available scientific evidence shows that the treatment has no beneficial effect(s) on the diagnosed condition and may even be harmful (3). Overuse, better described as overutilisation, is the 'establishment of standard practice in health services or systems that do not provide net benefit to patients or citizens' (3). Overutilisation does not necessarily lead to overdiagnosis or overtreatment, but the risk increases proportionally with the degree of overutilisation. When discussing the three concepts (overdiagnosis, overtreatment and overuse), it should be recognised that they can have different causes and drivers as to why they appear, and especially the consequences of overdiagnosis, overtreatment and overuse can be very different.

Overdiagnosis is an extremely harmful and big problem all over the world, and the problem is increasing. This is especially the case in high-income countries, where more sensitive tests, more testing, more screening and earlier diagnosis are in focus, and more of the same will be implemented in the future. Moreover, disease definitions have been, and are still being, widened, plus thresholds for treating, for example, risk factors have been, and are still being, lowered. Finally, disease mongering is growing, because it is cheaper and faster to invent new "diseases" than new pharmaceutical drugs.

From the definition of overdiagnosis it can be reasoned that a patient who has been correctly diagnosed and a person who has been overdiagnosed can have the same kind of deviations, abnormalities, risk factors or pathologies. Therefore, at the level of the individual person or patient, it can never be verified whether he or she has in fact been correctly diagnosed or overdiagnosed. Only at the end of the patient's life we can, for biomedical conditions, confirm whether the diagnosis was correct or iatrogenic. With respect to psychosocial conditions, illnesses and mental disorders, we can never, at the individual level, answer the question conclusively: Correctly diagnosed or overdiagnosed? Therefore, the complexity, dilemmas and pitfalls in understanding what overdiagnosis really is so succinctly captured by this quote from the Danish

philosopher Søren Kierkegaard (1813-55): 'Life can only be understood backwards; but it must be lived forwards'.

Overdiagnosis can be investigated both in phenomenological perspectives and in epidemiological designs.

Using a phenomenological perspective, informants who are most likely overdiagnosed or informants that have had the experience of being overdiagnosed (false positives) for a short period of time can be interviewed: Hansson et al. interviewed 15 men who, via screening, were (over) diagnosed with an abdominal aortic aneurism (AAA) with a median aorta-diameter of 32 mm (4). The AAA was by some of the men described as "a ticking bomb inside your stomach" (4). Another example from a qualitative study was focus group interviews with lung cancer CT screening participants who had had an abnormal screening result later confirmed to be false positive (5). In the critical period (the time period of three months or more from when the abnormal screening result was acknowledged to the point in time the screening participant was cleared of suspicion of lung cancer), these screening participants reported substantial negative psychosocial consequences from living with the uncertainty of possibly having lung cancer (5). The final example is a mixed-methods study, using a phenomenologically-based patient reported outcome measure, quantifying the psychosocial consequences of a false-positive screening mammography, in which more than 1,300 women were included (6). This study revealed that the women still reported substantial negative psychosocial consequences three years after the false-positive screening result (6).

A simple and very robust way to estimate the degree of overdiagnosis in a screening RCT (randomised controlled trial) would be to estimate the cumulative incidence of the condition screened for in the intervention group and in the control group (7). However, two types of biases are of importance: lead-time bias and contamination of the control group. A very didactical example of this is the European Randomized Study of Screening for Prostate Cancer (ERSPC): after 9 years of follow-up, the ratio between one prevented death of prostate cancer and men overdiagnosed with prostate cancer was 1:47, while this ratio decrease to 1:37 at the 11-year follow-up, and to 1:27 after 13 years of follow-up (8-10). Here it is obvious that lead-time is of importance; however, more than 20% of the men in control also had a PSA test in the ERSPC. These two biases, respectively, underestimate and overestimate the degree of overdiagnosis. Therefore, the "true" degree of overdiagnosis is hard to assess; however, it is substantial in PSA screening.

Harris and colleagues have suggested a taxonomy describing seven different categories of harms of screening that could be explored, namely: financial strain, hassles/

inconveniences, medical costs, opportunity costs, physical harms, psychological harms, and societal costs (11). In addition, we have identified empirical evidence for an additional category: work-related costs (12). These eight different categories of harms could also be applied to research about harms of overdiagnosis.

In many aspects of overdiagnosis, there is a substantial absence of scientific evidence, e.g. cancer screening (13). Internationally, there is, however, a growing awareness and interest in research about overdiagnosis, especially how to prevent it (14). But before we can answer these questions of how to decrease and prevent overdiagnosis, much more research is needed, e.g. about: the causes and drivers of overdiagnosis; the harms of overdiagnosis; the consequences of overdiagnosis; and how to communicate overdiagnosis to physicians, other healthcare professionals, politicians, healthcare providers and stakeholders, and most importantly, the general population.

## CONFLICTS OF INTEREST

The author reports no conflicts of interest.

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## ETHICAL APPROVAL

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